



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

SW

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/591,754	06/12/2000	Robert G. Walsh	11998.20US01	4758

34379 7590 07/01/2004

ACORN CARDIOVASCULAR, INC.
P.O. BOX 2903
MINNEAPOLIS, MN 55402

EXAMINER

MAIORINO, ROZ

ART UNIT PAPER NUMBER

3763

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/591,754

Applicant(s)

WALSH ET AL

Examiner

Roz Maiorino

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

1. Claims 1, 2-12-14, 19-26 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No.6432039 to Wardle.

Wardle teaches a device for treating cardiac disease of a heart having an upper and lower portions comprising a jacket 10 of flexible material defining a volume between an upper and lower end, the jacket adapted to be secured to the heart and adapted to be adjusted on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain circumferential expansion of the heart beyond the maximum adjusted volume during diastole and permit substantially unimpeded contraction of the

Art Unit: 3763

heart during systole; and a delivery source 326 for delivery of one or more therapeutic agents to the surface of the heart. The flexible material is polyester. Furthermore it teaches a delivery source covering (coating) part of the jacket.

2. Claims 1,3-26 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No.6077218 to Alferness.

Alferness teaches a device for treating cardiac disease of a heart having an upper and lower portions comprising a jacket 10 of flexible material defining a volume between an upper and lower end, the jacket adapted to be secured to the heart and adapted to be adjusted on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain circumferential expansion of the heart beyond the maximum adjusted volume during diastole and permit substantially unimpeded contraction of the heart during systole; and a delivery source or delivery of one or more therapeutic agents to the surface of the heart. Where the delivery source comprises of a separable element from the jacket where the separable element is the bioadhesive.

3. Claims 1, 3-26 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No.5713954 to Rosenberg et al.

Rosenberg teaches a device for treating cardiac disease of a heart having an upper and lower portions comprising a jacket of flexible elastic material defining a volume between an upper and lower end, the jacket adapted to be secured to the heart and adapted to be adjusted on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to

Art Unit: 3763

constrain circumferential expansion of the heart beyond the maximum adjusted volume during diastole and permit substantially unimpeded contraction of the heart during systole; and a delivery source for delivery of one or more therapeutic agents to the surface of the heart.

Response to Arguments

4. Applicant's arguments filed 84-13-2004 have been fully considered but they are not persuasive.

a. Applicant alleges Wardle does not teach **a device** that provides a non shifting contact between the therapeutic agent and the target surface of the heart. The above sentence is a function and intended use of the device in general and not the delivery source. Wardle teaches a device that provides an intimates and non shifting contact between the therapeutic agent and target cell. Applicant is claiming the above limitation reads on the delivery source however that is INCORRECT, the applicant has used the word "said device" which is in the preamble, and not delivery source, and even if he had used the word delivery source it still would NOT over come Wardle because it is functional intended use language, and Wardle is capable of having a delivery source that porives an intimates non shifting contact between the therapeutic agent and the heart

b. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., delivery device on the jacket) are not recited in the rejected claim(s). Although the claims are interpreted in light of the

Art Unit: 3763

specification, limitations from the specification are not read into the claims.

See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

c. Applicant alleges Rosenberg delivery's contains hydraulic fluid, which differs from the applicant's therapeutic delivery. However therapeutic material can be considered anything that helps the body improve, which including hydraulic fluid.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

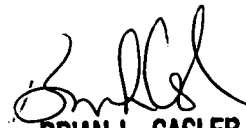
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Maiorino whose telephone number is 703-305-2336. The examiner can normally be reached on 9am-5:30pm.

Art Unit: 3763

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RM



BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700